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EXAMINER

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1617

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 24

Application Number: 09/468,777
Filing Date: December 21, 1999
Appellant(s): HASEBE ET AL.

Richard Lee Chin
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 1/18/02.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The

Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 11-21 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,679,357	Dubief et al.	10/1997
5,306,488	Vanlerberghe et al.	4/1994
4,152,272	Young	5/1979
5,476,661	Pillai et al.	12/1995
EP 487958	Nakamura et al.	6/1992

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(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. (EP 0487958) in view of Vanlerberghe et al. (5,985,255) or Young (4,152,272).

Nakamura et al. teach cosmetic compositions comprising 0.05-30% of an amphiphatic lipid, 0.05-30% of a nonionic surfactant, 1-50% of an ionic surfactant, and 40-99% of an aqueous medium, in which the amphiphatic lipids are stably microdispersed. Ceramides of formula (I) of the instant invention are disclosed as suitable amphiphatic lipids. Suitable nonionic surfactants disclosed include polyoxyethylene sorbitan fatty acid ester and polyoxyethylene alkyl ether. The reference fails to teach the numerical size of the amphiphatic lipid. See pg. 2, line 33-pg. 9, line 9.

Vanlerberghe et al. teach cosmetic compositions for use as hair care products. Particles, such as ceramides, having an average diameter between 0.1-200 μm are disclosed as known in the art. See Col. 1, line 8-Col. 2, line 11.

Young teach fabric conditioning compositions containing particles of 0.1-200 microns. Disclosed is an aqueous composition comprising a wax-like substance and cationic surfactant. It is disclosed that although fabric softening compositions are highly preferred embodiments of the

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present invention, other types of products utilizing wax/perfume particles are possible, for example hair conditioners. See Col. 1, line 45-Col. 8, line 42.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Vanlerberghe or Young into the invention of Nakamura and obtain a dispersion comprising amphiphatic lipid, surfactant, and an aqueous medium, wherein the lipid has an average particle size of 0.5-150um because a) Nakamura teaches his dispersion as a microdispersion, wherein the definition of micro is 1.a. Small:

microcircuit. b. Abnormally small: microcephaly. c. Requiring or involving microscopy: microsurgery.

2. One-millionth (10^{-6}): *microampere*.¹; b) Nakamura teaches his amphiphatic lipids as ceramides, higher alcohols, glycolipids, and cholesterol, all of which can be characterized as waxes; c) Young and Vanlerberghe teach aqueous dispersions comprising waxes, such as ceramides, wherein the waxes have a particle size of between 0.1 and 200 microns; d) all three references teach compositions comprising wax constituents, surfactant and aqueous medium; e) all three references teach cosmetic embodiments of their compositions.

Claims 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubief et al. (5,679,357) in view of Vanlerberghe et al. or Young.

Dubief et al. teach cationic dispersions based on ceramides and/or glycoceramides. Disclosed are compositions comprising ceramide of formula I of the instant invention and cationic surfactant in an aqueous medium. Ceramides and surfactants are disclosed as

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comprising 0.05-15% of the composition. The reference fails to teach the numerical size of the amphiphatic lipid. See Col. 1, line 24-Col. 10, line 28.

Vanlerberghe et al. is applied as discussed above.

Young is applied as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Vanlerberghe or Young into the invention of Dubief et al. and obtain a dispersion comprising amphiphatic lipid, surfactant, and an aqueous medium, wherein the lipid has an average particle size of 0.5-150um because a) Dubief teaches compositions comprising ceramides, which can be characterized as a wax; b) Young and Vanlerberghe teach aqueous dispersions comprising waxes, such as ceramides, wherein the waxes have a particle size of between 0.1 and 200 microns; c) all three references teach compositions comprising wax constituents, surfactant and aqueous medium, and Dubief and Young both teach cationic surfactants; d) all three references teach cosmetic embodiments of their compositions; e) all three references specifically teach hair compositions as cosmetic embodiments.

Claims 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pillai et al. (5,476,661) in view of Vanlerberghe et al. or Young.

Pillai et al. teach cosmetic compositions for topical application to skin, hair, and nails. Amphiphatic lipids of formula I of the instant invention are disclosed as comprising 0.0001-50% of the composition and surfactants are disclosed as comprising 0.5-30% of the compositions. Surfactants disclosed include alkoxylated compounds based upon fatty alcohols, fatty acids and sorbitan and alkyl polyglycosides. Dispersants are disclosed as cosmetic vehicles and water is

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exemplified as an aqueous vehicle. See Col. 4, line 24-Col. 11, line 61; Col. 13, line 45-line 67; Col. 22, line 30-Col. 25, line 3. The reference lacks teaching numerical average particle sizes.

Vanlerberghe et al. is applied as discussed above.

Young is applied as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Vanlerberghe or Young into the invention of Pillai et al. and obtain a dispersion comprising amphiphatic lipid, surfactant, and an aqueous medium, wherein the lipid has an average particle size of 0.5-150um because a) Pillai teaches compositions comprising 25-OH-D3 and ceramides, both of which can be characterized as waxes; b) Young and Vanlerberghe teach aqueous dispersions comprising waxes, such as ceramides, wherein the waxes have a particle size of between 0.1 and 200 microns; c) all three references teach compositions comprising wax constituents, surfactant and aqueous medium; d) all three references teach cosmetic embodiments of their compositions; e) all three references specifically teach hair compositions as cosmetic embodiments.

(11) Response to Argument

Appellant argues, "There is no motivation provided by the secondary references to formulate the composition of Nakamura et al. to have the amphipathic lipid present as a solid particulate of the claimed particle size, as Nakamura et al. teaches that the lipid and surfactant are to be melted together to form a new liquid crystal phase". This argument is not persuasive. First, the Examiner respectfully points out that arguments toward the method of making the composition are not commensurate in scope with the instant composition claims. Second, the

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Examiner respectfully points out that the lipids were present as particles, which are solid. On page 2, line 36 of Nakamura et al., the amphiphatic lipids are disclosed as being microdispersed in an aqueous medium, on page 2, line 20, the amphiphatic lipids are disclosed as solid at room temperature (25 C), and on page 2, line 35 the composition is disclosed as being in a semi-transparent state. Thus, the amphipathic lipids of Nakamura et al. are solid particulates.

Furthermore, while Nakamura et al. does not teach the numerical value of the particles size of the amphipathic lipids, they do teach that the amphipathic lipid particles have a micrometer size range.

Appellant argues, "Evidence that the amphipathic lipid is not present as a solid particulate having an average particle size of 0.5 to 150 um is found in the reported phase change of the amphipathic lipid from being a solid, to existing as an anisotropic liquid crystal phase in conjunction with the surfactant. This actually teaches away from forming amphipathic lipid particles of the claimed particle size range, as the reference does not even suggest discrete particles of amphipathic lipid". This argument is not persuasive. The Examiner respectfully points out that while the lipid and surfactant are mixed and melted, the reference also states that "after cooling to room temperature (the lipid and surfactant) a lipid microdispersion is obtained (pg. 4, lines 19-20)", and that the reference teaches the amphipathic lipid as a solid at room temperature. Furthermore, the Examiner respectfully directs Appellant to the teaching of Vanlerberghe et al, which disclose a) stable wax microdispersions having particle sizes lower than 500nm (0.5 micrometers); b) ceramides as waxes; c) and microdispersions with waxes as producing stable compositions that are dilutable with water and without aggregation and sedimentation of the particles in suspension. And, Vanlerberghe et al. teach that the wax

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microdispersions are obtained by melting the wax (ceramide amphipathic lipid) in the presence of a surfactant and that upon cooling, a stable microdispersion of solid colloidal particles of wax (ceramide amphipathic lipid) are obtained (see Col. 1, lines 40-56). Thus, one of skill in the art would be motivated to teach the microdispersed ceramide amphipathic lipid of Nakamura et al. as having the particle size of 0.5 micrometers, as disclosed by Vanlerberghe et al, because of the expectation of achieving a stable and dilutable cosmetic composition and because Nakamura et al. already teach their lipids as microdispersed and as being melted together with a surfactant and then cooled. See Col. 16, lines 47-51 of Vanlerberghe et al, wherein "ceramide" is taught as a wax and see pg. 2, line 50 and formula (I) on page 3 of Nakamura, wherein the ceramide is taught as the amphipathic lipid.

Appellant argues, "Nakamura et al. describes a very different structure from that claimed, in that the lipid and surfactant are melted, which together form an anisotropic liquid crystal phase. In such a structure the lipid is not dispersed in the surfactant and aqueous medium, but rather the lipid and surfactant have formed a new liquid crystal phase. Accordingly, the cited reference fails to teach the claim limitation of the amphipathic lipid being dispersed in the surfactant and aqueous medium". This argument is not persuasive. Again, the Examiner respectfully directs Appellant to Col. 1, lines 41-56 of Vanlerberghe et al., which teaches wax (ceramides) microdispersions having a particle size of 0.5 micrometers, wherein the wax and surfactant are melted together and then cooled to room temperature to obtain a stable microdispersion of solid colloidal particles.

Appellant argues, "Nakamura et al. describes a process in which lipid and surfactant are melted together, then aqueous medium is added. . . The aqueous medium is not added, until after

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the lipid and surfactant have been melted together. As such the reference fails to disclose or suggest a dispersion or process in which the lipid, surfactant, and aqueous medium are heated together at not less than the melting point of the lipid". This argument is not persuasive. The Examiner respectfully reminds Appellant that the rejection was made over the combination of Nakamura et al. in view of Vanlerberghe et al. or Young. The Examiner respectfully points out that Vanlerberghe et al. teach that the wax microdispersions are obtained by melting the wax in the presence of surfactant, optionally with water to obtain the microdispersion. Thus, adding the water during melting or following melting is interchangeable, as Vanlerberghe et al. teach the addition of water in either step.

Appellant argues, "Nakamura fails to disclose or suggest a cosmetic composition which is a wash-away type, in any way". This argument is not persuasive. First, the recitation "washing away-type" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Second, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re*

Otto, 136 USPQ 458, 459 (CCPA 1963). In the instant case the intended use of the instant composition of washing away the composition after application to the skin or hair, is not given patentable weight, as it does not result in a structural difference.

Appellant argues, "Like Nakamura et al. described above, Dubief et al. describes a composition prepared by melting the surfactant and lipid, then adding water. The result is an emulsion and not a dispersion as claimed. There is no disclosure of the lipid being present as a solid particulate, as claimed. There is no disclosure of the lipid having an average particle size of 0.5 to 150um". These arguments are not persuasive. The Examiner respectfully points out that Appellant's arguments are directed toward the references individually when the rejections were made over a combination of references. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Examiner respectfully reminds Appellant that Vanlerberghe et al. was combined with Dubief et al. to teach particle size and the preferred methods of making the dispersion. Dubief et al. teaches cosmetic compositions comprising dispersions comprising ceramides. Vanlerberghe et al. teach cosmetic compositions comprising microdispersions comprising waxes, such as ceramides. Vanlerberghe et al. further teach their method of making and their particle size as producing cosmetic compositions that are stable and dilutable with water without limitation and without aggregation and sedimentation of the particles in suspension. Thus, one of skill in the art would be motivated to teach the ceramides of Dubief et al. as having the particle size taught by Vanlerberghe et al. because of the expectation of

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achieving a composition that is stable, dilutable with water, and without aggregation and sedimentation.

Appellant argues, "The invention of claims 12 and 13, which recites that the surfactant is one of a nonionic, anionic, amphoteric surfactant is not rendered obvious by the cited reference which is specifically limited to cationic surfactants". This argument is not persuasive, as Col. 4, lines 17-23 teaches that anionic and nonionic polymers can be added to the composition.

Appellant argues, "Pillai et al. does not disclose any solid particulates or particle size whatsoever" and "The claim limitation of the heating of the lipid, surfactant and aqueous medium, together to a temperature of not less than the melting point of the lipid is a claim limitation which is not found in the cited references". These arguments are not persuasive. Again, The Examiner respectfully points out that Appellant is arguing against the references individually when the rejection was made over a combination of references. The Examiner respectfully points out that Vanlerberghe et al. was relied upon to teach the particle size of the lipids and a method of making the dispersion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the ceramides of Pillai et al. as having the particle size taught by Vanlerberghe et al. because of the expectation of achieving a stable composition that is dilutable with water, and without aggregation and sedimentation.

Appellant argues, regarding Pillai et al., "The references fail to disclose or suggest a wash-away type cosmetic composition". This argument is not persuasive. First, the recitation "washing away-type" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does

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not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Second, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case the intended use of the instant composition of washing away the composition after application to the skin or hair, is not given patentable weight, as it does not result in a structural difference.

Appellant argues, "The metes and bounds of the term 'psuedoceramide' is clear to those of ordinary skill in the art, as evidenced by the use of this term in claims of issued U.S. Patents". The rejection of this term under 35 USC 112, 2nd paragraph, was overcome by the arguments in Paper No. 16 and noted by the Examiner in Paper No. 18.

Lastly, regarding particle size, the Examiner respectfully reminds Appellant that a) it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 233), and b) Selection of particle size is not a patentable modification in the absence of unobvious results. *In re Rose*, 105 USPQ 237 (CCPA 1955).

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

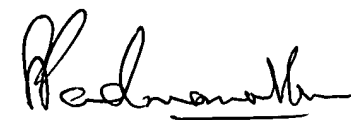
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